PHARMACEUTICAL SYSTEM PERFORMANCE WITHIN THE CONTEXT OF HEALTH SECTOR REFORM

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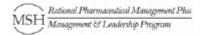
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BACKGROUND

In the early 1990s, the convergence of social, economic, and political factors in Latin America triggered what is known today as Health Sector Reform (HSR). Among these factors were the consolidation of market economies; the increasing costs of health care; the renewed importance of human capital as an engine of economic development; and a perceived inefficiency and inequity of the public sector, particularly in the areas of health and education. Within this context, the Inter-American Development Bank (IDB) and the World Bank made a decision to include HSR in their technical and financial agendas for the region (PAHO, 2002). With their support, by the end of the decade most Latin American countries were somewhere between the design phase and the initial implementation phase of reform. In 1997 the USAID Latin America and Caribbean Regional Bureau funded the Latin America and Caribbean Health Sector Reform (LAC/HSR) Initiative in recognition of the need to support the implementation and evaluation of reform efforts, and in 2002 the Rational Pharmaceutical Management Plus (RPM Plus) program was invited to participate in the initiative.

Although public health sector reforms differ from country to country, most of the planned reforms adopted similar approaches and combinations of strategies that considered decentralization, separation of functions, increased social participation, contracting services from the private sector, adapting alternative administrative, financial and clinical care models. These strategies have presented particular opportunities and challenges for the design and management of the pharmaceutical system, a key support subsystem of the larger health care system. However, although public sector pharmaceutical supply systems in the region have been undergoing changes, decisions to change these systems have not always been able to benefit from an analysis of lessons learned from reform experiences.

As its contribution to the LAC/HSR initiative, RPM Plus has prepared this guidance document for health system planners and managers to use as they think through how to ensure the effective and efficient functioning of the pharmaceutical system within the context of health sector reform.

INTRODUCTION

Health reform initiatives can present new opportunities and challenges for improving the performance of health care systems. Reform proposals are often bold undertakings that involve some degree of reconfiguration, reorganization, and restructuring of the way health services are managed and financed. The *sine qua non* of most modern health care services is pharmaceuticals[1] and despite significant expenditures on pharmaceuticals, public and private, large segments of the population in many countries still do not have access to safe, effective, low-cost medicines (WHO, 2004). Arguably, pharmaceuticals are such a powerful symbol of health care services that lack of access to them can signal the failure of health sector reform initiatives, and can be politically devastating to a government (political liability).

Throughout the 1990s, numerous countries in the developing world embarked on health sector reforms and researchers and planners began to formalize conceptual models and methods for measuring the performance of health systems against important outcomes such as access, equity, and quality of care (c.f., Knowles et al, 1997; Murray and Frenck, 2000). Out of this grew an appreciation for the complexity of actions and changes required to affect the desired reactions and adjustments in such complex entities as a health system (e.g., Mills, et al, 2001; Roberts et al, 2004), including the supporting subsystems (PAHO 2002). However, despite the recognized centrality of pharmaceuticals to quality of service delivery, the factors impacting the subsystem's ability to ensure the availability of pharmaceuticals may be inadequately integrated or uncoordinated with other reform efforts (e.g., Romero et al, 2002).

This paper describes an evidence-based approach for the critical and systematic analysis of a pharmaceutical system that is largely consistent with the step-wise approach of Roberts et al (2004), presented in Diagram 1. This approach is general and not specific to the Latin American context, but examples from Latin America are presented to illustrate particular points.[2] The document begins with a presentation of the key functions of a pharmaceutical system. It follows with discussion of how performance goals can be measured. The overall approach promotes the use of standard indicators to evaluate system strengths and weaknesses and identification of appropriate intervention points. Reforms are implemented through any one or combination of four types of instruments that include policies and laws, financing mechanisms, reorganization of services and behavior change. Specific examples of instruments that have impacted pharmaceutical systems in Latin America are discussed.

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[1] Pharmaceuticals are defined as medicinal products, vaccines, contraceptives, and the diagnostics and medical supplies needed to ensure the safe and effective use of medicinal products.

[2] It is not the intent of this document to provide a comprehensive review of the evolution or evaluation of health sector reforms. Background documents covering these topics may be found at http://www.lachsr.org/es/index.cfm.

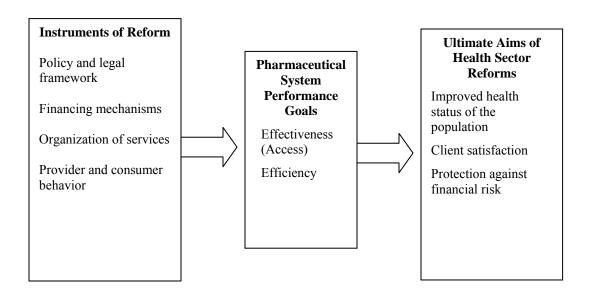| Instruments of Reform		Pharmaceutical System Performance Goals		Ultimate Aims of Health Sector Reforms
Policy and legal framework Financing mechanisms Organization of services Provider and consumer behavior	⟹	Effectiveness (Access) Efficiency	⟹	Improved health status of the population Client satisfaction Protection against financial risk

Diagram 1: Framework for evaluating pharmaceutical systems (adapted from Roberts et al., 2004).

HEALTH CARE SYSTEMS AND PHARMACEUTICAL SYSTEMS

Assessments of health system performance often include questions of the availability of key pharmaceuticals at the facility level as a measure of quality of care (Knowles et al, 1997). Indeed, it is widely recognized that the ability of health care systems to successfully address most modern health problems rests largely on the availability of these products, and that people will seek care when they are available. As such, we can conceptualize the pharmaceutical supply system as a critical subsystem of the larger health system whose effective functioning is essential to access to and use of health care services (see Diagram 2).

Pharmaceutical management is defined as the set of practices around four key functions that are aimed at ensuring the timely availability and appropriate use of safe, effective, quality pharmaceutical products and services in a given health-care setting. A pharmaceutical supply system is defined by the procedures and methods used to accomplish these key functions.

Diagram 2: Health and pharmaceutical systems

The parameters that determine how these practices may be performed are determined by prevailing laws and regulations such as those regarding the import/export, manufacture, sales and use of medicines, as well as laws that govern general labor, commercial and financial matters. How and, to a great extent, how well a pharmaceutical system performs is mitigated by the availability and quality of human and financial resources, and the relative priorities for these scarce resources are expressed through national development, health and pharmaceutical policies.

The next section describes the key functions of the pharmaceutical system. Many of these functions are often directly addressed through reform initiatives where as in other cases they are impacted indirectly. The following section discusses how the performance of a pharmaceutical system may be measured to identify how opportunities for improvement and impact of health sector reform initiatives.

DESCRIBING THE FUNCTIONING OF A PHARMACEUTICAL SYSTEM

This section provides an overview of the key functions of a pharmaceutical system. These functions must be carried in any system, although how they are accomplished may vary from system to system, and many health reform initiatives can be observed to directly and indirectly impact on these functions. One reason for this is that the management of pharmaceutical supply is cyclical in nature. As such these functions are characterized by dependent relationships whereby the quality of one function can affect the quality or outcome of another (see Diagram 3).

Selection

The number of pharmaceutical products marketed in any given country can be in the thousands, yet only a few may be of direct relevance to the most important public health problems in the country. Being able to distinguish between those that are most useful and restrict practitioner choices to these selected products is of clinical and financial significance to health systems.

Diagram 3: Functional components of a pharmaceutical system

The selection function includes the decisions and actions required to determine which products will be permitted to circulate in the system. The priorities and criteria for selection are typically detailed in a national health or drug policy and should correspond to the clinical and therapeutic needs of the population, as well as meeting acceptable standards for product safety, efficacy, quality, and cost-effectiveness (WHO, 2002). Selection should also reflect appropriateness for the level of care (products needed at the clinic level are different than those needed at the hospital level). The output of a selection process may take the form of a national formulary or essential medicines list, typically with the pharmaceutical products listed by international non-proprietary name (INN).

The use of INNs aids in avoiding reliance on any single brand name and helps to focus on the particular molecule of interest. When used to guide procurement, much like a shopping list, essential medicines lists are cost control tools by preventing purchases of non-essential or "luxury" items. Health systems seeking to improve efficiencies to be able to improve some dimension of effectives (availability, affordability, access, acceptability) will always be well served by implementing or updating and maintaining national essential medicines lists.

The primary responsibility for the selection of pharmaceuticals for most public health systems is at the national level, to take advantage of the expertise and technical resources available at that level, although there may be mechanisms to allow for some local adaptation. There are strong forces that may not support the concept of a national essential list, most notably pharmaceutical manufacturers that feel that they will be blocked from accessing a potential market for their

goods. Selection committees need adequate training and recognition, and the support of a national policy or legislation to be able to carry out their function in a transparent manner. National regulatory processes, particularly registration, should support the selection function to ensure that selected products are available to be marketed in the country and that adequately trained health professionals are available to ensure their appropriate use.

Procurement

The goal of the procurement function is to assure that the right quantity of quality products are purchased at the best price possible and that they are delivered when expected. Key activities under the procurement function include quantification of needs, purchase, receipt, and payment. In established systems with centralized procurement, quantification usually involves a methodology of obtaining information from the facility level on actual consumption and aggregating it to the level where procurement is realized. Weaker systems however, may need to rely primarily on historical data, previous quantities sent to the facilities, or population based estimates rooted in expected services utilization used to determine quantities to be ordered at the national level.

The strategies (e.g., centralized or decentralized) and methods (e.g., international competitive tenders, restricted tender, competitive negotiation, direct procurement) that may be employed to procure supplies are determined by the prevailing laws and regulations that govern the system, and should be appropriate for the types of products sought, budgetary cycles, and available financing mechanisms. As most centralized systems are based on an annual fiscal cycle, procurement is typically an annual exercise, although small procurements throughout the year may take place for emergency purposes or for special products. These large procurements lend themselves to international competitive bidding and benefits of economies of scale. However, one of the problems with highly centralized systems is that they may be too cumbersome to be responsive to local variations; needs and incentives are often not in place to curb waste and loss at the local level.

Some reform initiatives have sought to improve efficiencies and grant more autonomy to the local levels through decentralization and deconcentration of procurement functions. However, specifically with respect to pharmaceutical procurement, this can be problematic. The potential problems associated with complete decentralization and deconcentration include loss of economies of scale, decreased access to suppliers, lack of local expertise to evaluate needs, prepare procurement documents and make purchases, as well as reduced access to quality assurance mechanisms (e.g., Barillas, 2005b).

In the course of realizing larger reforms that aim to achieve the benefits of more decentralized management of public health services, some countries have opted to retain some procurement functions at the central level. For example, public tenders with qualified suppliers can take place at the national level to preserve economies of scale and to address critical quality assurance issues, while actual purchases are made from these pre-selected suppliers at the tendered price (e.g., Brazil, Guatemala, Ecuador, and Peru). Where fiscal responsibilities are deconcentrated, resources may also be pooled at subnational levels to create buying groups in order to gain some economies of scale, as has occurred in Peru and El Salvador. Regardless of the plan, there

remains a need for local fiscal controls and functional management systems to ensure that needs estimates and quantifies for procurement are accurate, reliable and up to date, and that funds are available as planned.

Distribution

The distribution function covers both storage and transportation of items procured and it should aim to ensure the flow of products to the facilities with a minimum of waste and loss. Inventory management, a core responsibility in this component of the cycle, involves close monitoring of the movement of stock both into and through the system. This information is used to guide procurements, as well as to ensure that there are no stock outs of gluts throughout the chain.

Centralized systems are characterized by one or two central medical stores that receive procured items and process orders from lower level facilities. Larger countries are more likely to have multiple stores. A multi-tiered system generally requires greater consideration of expiry periods, and offers increased opportunities for loss due to damage and theft associated with transportation from one level to the next. Transportation may be the responsibility of the central store or of the lower levels.

Storage and transportation represent significant recurrent costs for Ministries of Health and, as such, are the most obvious for consideration for privatization or contracting out. Options to this effect are limited by laws regarding disposal and replacement of government property, restrictions on privatization and contracting of services, and civil service laws. For this reason, however, opportunities to explore alternatives arise when countries undergo larger reforms that may not be specific to the health sector. For the distribution component, for example, one alternative to the classic medical store model is to have supplies delivered directly from the supplier to the service delivery point. Stipulations for this can be written into the procurement documents. This type of distribution system requires that suppliers have the capacity to make programmed deliveries and the capacity on the part of the facility to appropriately program shipments and to receive and store supplies. It also requires that allowances be made to otherwise make use of public facilities and personnel.

Use

This function of the pharmaceutical system refers to the behaviors and practices associated with prescribing, dispensing and actual consumption of pharmaceuticals. The concept of rational drug use encompasses the constellation of factors that lead up to the availability of pharmaceuticals (selection, procurement, distribution) as well as ensuring that the desired therapeutic outcomes are achieved. Whereas public health systems might focus on public sector provider behavior, many countries also aim to align the behaviors of private practitioners with public health concerns.

Interventions to improve the use of pharmaceuticals include development and enforcement of laws and regulations regarding selection and the sale of certain products or the actions of prescribers and dispensers. Drug laws specify the types of facilities that may dispense or sell

drugs, and who may prescribe certain products. Registration and inspection procedures aim to support enforcement of these laws and regulations. In many countries however, the ability to conduct these activities is weak to non-existent.

Other types of interventions may be educational or informational in nature, or managerial. The development and use of standard treatment guidelines represent a type of intervention that aims to influence prescribing behavior through information. Providers may be trained with these guidelines, but when supported by managerial interventions (such as supervision and drugs and therapeutics committees), the desired behavior is more likely to be achieved and sustained.

Managerial Support

The component of managerial support includes the financial, human and informational resources required to ensure the effective functioning of the supply system. Many of the targets of sectoral reform and "modernization" in general impact directly on this component. Of particular relevance to the pharmaceutical system are questions about changing financing systems, civil servant reforms, and changes in the locus of decision making for all other components of the pharmaceutical system. Without the requisite management support, the entire system can screech to a halt. Health sector reforms typically will heavily impact on this function of the supply cycle.

Among the greatest challenges facing health systems is the shortage of qualified human capacity in management and clinical areas. The causes of shortages include the maldistribution of staff (concentration in urban centers), lack of resources to recruit, train and support health workers, and migration of qualified staff to areas that offer more opportunities for professional growth and development (MSH, 2004). This has also impacted the availability of staff to carry out the functions of the pharmaceutical system. Shortages of pharmacists and other pharmacy professionals have forced the question of what functions can be responsibly carried out by other health care staff, such as nurses or pharmacy assistants, provided they receive appropriate training.

EVALUATING THE PERFORMANCE OF A PHARMACEUTICAL SYSTEM

A significant portion of all health expenditure is related to the pharmaceutical system and, for this reason, health planners, whether within the context of health sector reform or not, should be concerned about being able to measure the performance of their pharmaceutical system. Within the context of health sector reform, being able to compare the performance of the incumbent system with an alternative or modified model is extremely informative for decision-makers responsible for proposing or accepting reform initiatives. Evaluations of performance will allow the determination of whether or not initiatives have had the intended impact.

The performance of a pharmaceutical system may be evaluated in terms of effectiveness (are the outcomes achieved) and efficiency (the level of inputs are required to achieve outcomes). Evaluations are necessarily comparative in nature. Comparisons may be made with the performance of other health systems (social security versus Ministry of Health versus private sector). Being able to measure and monitor performance over time is clearly useful to determine if targets are being met and if adjustments are merited. To the extent that pharmaceutical systems support the larger health care system, the performance of the latter system is dependent on the performance of the former and for this reason, many of the criteria for evaluation of each system correspond to each other.

The following sections define important performance dimensions for the pharmaceutical system. Key indicators are presented. The data needs for these indicators may be obtained from standard reports generated from health information systems, health accounts information, and drug management information systems. However, in many cases, data is simply not available for various reasons: information systems that were created prior to reforms did not allow for some of the line items of interest following said reform; information is not available in the format needed for analysis; information is too incomplete because the systems in general are weak and ineffective (often an area for improvement under reform). As such, to obtain data required from the facility level requires a special effort.[3]

Effectiveness (Access)

The effectiveness of a pharmaceutical supply system may be defined by the degree to which it achieves access to essential, quality pharmaceuticals and pharmaceutical services (those services required to ensure the appropriate use of pharmaceuticals).

Access to pharmaceutical products and services has been operationalized to reflect four critical dimensions of access, each of which impact on overall health services utilization: availability, geographic access, affordability, and acceptability.[4]

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[3] The detailed methodology for how to conduct a pharmaceutical sector assessment is available in *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* by MSH (1995) and is available on http://erc.msh.org/mainpage.cfm?language=English&file=8.60.htm&module=toolkit

[4] See MSH/Strategies for Enhancing Access to Medicines (SEAM) background documents and country programs using this approach at http://www.msh.org/seam/3.1.htm .

- *Availability:* The continuous presence of the desired/selected product in the necessary quantities in the facilities where they should be found.

- *Geographic accessibility*: The relationship between where the product or service is located and the location of the eventual user of any of these (coverage).

- *Affordability:* The relationship between the price of the product or service and the ability of the user to pay for it.

- *Acceptability*: The relationship between the characteristics of the products and services offered and the user's/providers attitudes and expectations about the products or services.

♦ Availability of pharmaceuticals and pharmaceutical services

Health services depend heavily on the availability of essential medicines. For this reason, the regular availability of pharmaceuticals is considered a key indicator of quality health services. The regular availability of quality pharmaceuticals, and the services associated with their proper use may considered the quintessential measure of the effectiveness of a pharmaceutical system. The key indicators to measure availability are:

- Average percentage of a set of unexpired tracer pharmaceuticals available in a sample of pharmacies/dispensaries at a particular moment in time (day of visit).

- Average percentage time out of stock over a period of one year (at least as long as one procurement period) for a set of unexpired tracer pharmaceuticals in a sample of pharmacies/dispensaries.

- Presence of qualified provider/dispenser at the time of visit

Tracer pharmaceuticals are a subset of essential products that should be available at the type of facility studied. For this reason, the tracer list that would be used in primary care facilities will be different that the list that would be used at tertiary level facilities. It is also important to note that expired products that may be on the dispensary shelves are not considered to be available (although in reality they may be used anyway).

The determination of appropriate qualifications for providers and dispensers is based on the local laws and regulations and licensing requirement related to these functions. These qualifications should relate to the formal training received as well as any additional training that might be received, including continuing education.

Low levels of availability of pharmaceuticals may be related to failures in the procurement function, from inadequate quantification and budgeting through to poor supplier performance. Low levels of qualified providers may reflect low levels of enforcement, but may also reflect real human resources shortages.

♦ **Geographic accessibility**

This dimension of access reflects the issue of the distribution of services and equity. Geographic accessibility takes into consideration the time and distance required to access essential pharmaceuticals and services. Of particular interest are differences between urban and rural populations, but there may be other relevant comparisons in any particular context. The specific criteria for determining acceptable time and distances should be relevant for the particular context being evaluated. Indicators that may be used to assess this dimension of access include:

- Percent of population living more than two kilometers from a legitimate source of pharmaceuticals.

- Average time to walk to the nearest legitimate source of pharmaceuticals.

- Ratio of the average time to travel to nearest legitimate source of pharmaceuticals for urban and rural populations.

In many countries the private sector has a broader geographic reach than the public sector and for this reason partnering with the private sector, in particular with private pharmacies may be an interesting option for countries that aim to expand their geographic reach. The investment in public sector facilities may be better focused in areas where there are no natural market forces to attract private sector activity.

For the supply of pharmaceuticals in particular, it is important to note the distinction between legitimate and illegitimate sources of pharmaceuticals. In many countries, pharmaceuticals may be found in every marketplace, in the baskets of street vendors, and all varieties of shops. Although these sources of pharmaceuticals may be well distributed, they are not considered to be legitimate. Poor geographic distribution of legitimate sources may be related to adverse market forces, lack of qualified human resources, and poor enforcement of laws and regulations regarding the dispensing and sale of pharmaceuticals. Alleviating this problem inevitably requires strong political support to redirect resources to compensate for adverse market forces, and/or an investment in upgrading the skills and qualifications of illegitimate dispensers.

♦ **Affordability**

Economists define affordability as a relative concept that includes an appreciation of the notion of willingness to pay and price elasticity. From a pharmaceutical system perspective however, the measure of affordability is operationalized to consider comparative prices to the patient by unit and by treatment. Key indicators include:

- Average unit price differential between public sector and private sector for a set of unexpired, quality tracer pharmaceuticals.

- Average number of days of work required to pay for a standard recommended course of therapy for tracer conditions (indexed to income category).

- Ratio of average percent of income required to pay for a standard recommended course of therapy for tracer conditions between highest and lowest income quintiles.

As countries sought to expand services without being able to increase the public coffers, charging patients for health services, including pharmaceuticals became a more common way to finance health care. Various types of payment and cost recovery schemes were developed accordingly. Some schemes covered all pharmaceuticals as a flat fee, irrespective of the actual unit costs, and others charges separate fees for the clinical visit and the pharmaceuticals provided. Allowances may have also been made for special groups such as the indigent, women with small children, and the elderly. These different ways that prices are determined and how patients may have to pay for their treatments should be considered in the selection of appropriate indicators of affordability.

High price differentials may be related the penchant for branded or imported products in the private sector. If the procurement function in public sector is able to take advantage of economies of scale, the unit prices should reflect this relative to the prices in the private sector.

♦ **Acceptability**

This dimension of access relates most directly to the concepts of quality and satisfaction both from the provider and the client/patient perspectives. Indicators of acceptability include:

- Percent of clients/patients that report satisfaction with the outcome of the last visit to the public or private facility that dispenses pharmaceuticals.

- Percent of prescriptions that reflect current standard treatments for tracer conditions.

- Percent of facilities with source of up-to-date unbiased information about pharmaceuticals for providers

- Percent of facilities with source of up-to-date unbiased information about pharmaceuticals for patients.

- Presence of expired or unregistered products in dispensaries/pharmacies.

Reporting on levels of client/patient satisfaction with pharmaceutical services requires an understanding of the expectations for the services. This can be a problem when there is a very limited notion of the potential for the services and expectations are very low. For this reason movements that aim to defend client/patient rights also have an educational component to raise awareness, and expectations.

Improving access to services, and therefore medicines, is one of the main goals of most health sector reforms and as such, is the most commonly measured indicator. As reforms gain momentum and experience with implementation, increasing numbers of studies are being published that examine the effectiveness of the reforms using clear measures of access (e.g., Restrepo et al, 2002; Romero, 2002). There is much less information about the impact of reform initiatives on the efficiency of the pharmaceutical system.

Efficiency

Efficiency is a measure of effectiveness that specifically focuses on the relationship between inputs (generally financial and human resources) used to achieve desired outputs (effect). In terms of pharmaceutical systems, we can consider measuring the efficiency with which each major component or function of the cycle is accomplished in order to ensure that quality pharmaceuticals are available where and when needed. Measures of efficiency compared over time or across systems are used to identify opportunities for cost reduction or the need for cost increases. Ultimately, as pharmaceuticals and the management of the pharmaceutical system represent one of the biggest costs to the health system (financial costs as well as the political costs associated with nonperformance) the efficiency of a pharmaceutical system impacts on the sustainability of the larger health system. For this reason, ensuring that efficiencies are regularly addressed should be a central concern for those involved in the design of health reform initiatives.

♦ **Allocative Efficiency**

Many health sector reforms seek to expand the reach of health services to previously underserved populations. Allocative efficiency refers to whether or not the health budget and expenditures reflect the priorities of the system. For example, a system that aims to assure access to primary care services to the population, the larger share of the drug budget would be expected to be spent on essential drugs as opposed to drugs typically used only in specialized tertiary care facilities. There are several indicators that may be used to compare spending on pharmaceuticals to address the question of "how much" is enough. Many of these indicators do not allow for separating the costs of managing the pharmaceutical system from the prices paid for pharmaceuticals, but they may be used to gauge performance against programs in countries in the same region and with similar levels of development and gross domestic product. Comparisons between relevant subgroups of the population (by income level or special interest group) will also yield information that may influence allocative decisions:

   o Per capita pharmaceutical expenditure

   o Pharmaceutical expenditure as a percentage of GDP

   o Private spending for pharmaceutical as a percentage of total spending on pharmaceuticals

   o Pharmaceutical expenditure as a percentage of total health expenditure

   o Out-of pocket expenditure on pharmaceuticals as a percentage of household income

♦ **Technical Efficiency**

Technical efficiency refers to how well each function of the pharmaceutical cycle performs. It is much more difficult to measure and yet where many health reform initiatives have a significant impact. Technical efficiency addresses both therapeutic decisions (selection and use) and operational issues (management, procurement, and distribution).

Therapeutic efficiency is addressed through the establishment and maintenance of essential drugs list or formularies and drug utilization reviews. Expenditure and consumption data can be evaluated by therapeutic category to determine if use reflects what would be expected or is appropriate given morbidity data. Savings might be incurred by identifying therapeutic duplications or by substituting less costly products for more costly ones from the same therapeutic category. Drug utilization reviews may also reveal irrational prescribing practices that result in more expensive treatment costs. Because this type of evaluation requires access to good information and skills to evaluate it, the responsibility for ensuring therapeutic efficiencies rests with qualified pharmacy and therapeutics committees (PTCs), which may exist only at the national level in several countries, and even then the PTC may not have the skills to conduct this type of evaluation.

Health sector reforms that raise the possibility for contracting and privatizing services are generally based on the notion that greater o*perational efficiencies* will be gained. The initiative is related to efforts to "modernize" traditionally heavily bureaucratic systems stymied by civil servant laws and the recognition that the private sector, particularly in a competitive environment, has incentives to maximize efficiencies. However, options for working with the private sector should always consider the strength and maturity of the private sector and the level of competitiveness. Reform planners that do not conduct a serious evaluation of the private sector prior to designing and implementing initiatives calling for a larger role of the private sector may be very disappointed.

There are four cost categories from which key indicators of pharmaceutical system performance are derived.[5] These are:

Acquisition costs: the cost of making the regular planned purchases of pharmaceuticals in a period reviewed (usually a budget cycle, or one year). This is not just the prices paid for the products but also includes any additional fees and charges (such as those for shipping and insurance) associated with the procurement. This information is usually readily available from a procurement office. If procurement is conducted at lower levels, this information should also be captured for the analysis.

Purchasing costs: as opposed to the acquisition costs, these costs are related to the act of realizing the purchases. It includes the salaries of those involved, supplies, and communication costs related to managing tenders, placing purchase orders and receiving goods. This information is often difficult to obtain, in part because it is unlikely to be available in any one place or compiled in a way that is easy to assess. Personnel costs may not be tracked in a way to determine who is involved in the procurement process, how much of their time is actually spent on these activities, and what portion of all supplies are used specifically for procurement. In these situations (which is very common) estimates need to be determined based on available data.

Inventory holding (distribution) costs: all costs associated with managing inventory, including rent for warehouses, utilities, salaries, communications, equipment (including depreciation), other supplies, as well as transportation-related costs (fuel, maintenance, repairs), costs associated with inventory loss due to wastage, theft, and expiry. Many of these costs may be

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[5] A more comprehensive discussion is presented in MSH, *Managing Drug Supply.* (1997), pp 645-649.

available at a medical store, but some are costs that are only captured at the national level so estimates would be required. The costs should be obtained from all levels of the system (e.g. regional and district stores).

Shortage costs: quantifiable costs include expenditures on emergency purchases (generally available) and estimates of revenue loss (if cost recovery is in place); more difficult to quantify are costs associated with increased morbidity and mortality that may result from stock outs, and the political cost of loss of goodwill from beneficiaries.

A comparative analysis of the performance of the incumbent system with another system in operating in the same country is extremely useful for identifying potential areas for improving efficiencies. Public and private for-profit sector comparisons are the most common, although comparing the performance of NGOs is also very useful. Key indicators of efficiency to assess include:

♦ The average percentage difference between unit prices paid for a set of selected items and comparable prices paid (at appropriate levels). Although the acquisition costs include the prices paid and any associated fees, the prices alone can be evaluated. Factors impacting on prices include economies of scale and level of competition. International competitive bidding, for example, tends to maximize opportunities for competition among suppliers for most products. Prices paid for products obtained through local or emergency purchases can be compared with prices paid for tenders, but it would not be appropriate to compare international tender prices with retail prices. [6]

♦ Purchase costs as a percentage of drug acquisition costs, to compare the efficiency of the purchasing function. As each procurement implies purchase costs, the number of procurements should be minimized.

♦ Inventory loss (due to expiry, theft, damage, etc.) as a percentage of average inventory value. Private sector values tend to be lower than those of the public sector.

♦ Average inventory turnover, calculated as the value of products distributed divided by the average inventory value. Although influenced by the procurement cycle to some degree, it is an indicator of whether the holding cost is reasonable. In the private sector, the turnover may be nearly monthly, while three to six turnovers per year are more common in public systems.

♦ Personnel costs, space costs, transport costs, and other direct operating costs as a percentage of total holding costs. These measures are used to evaluate the relative proportion of total costs attributable to each category of costs.

♦ Total holding cost as a percentage of the value of pharmaceuticals distributed (or average inventory). This is a measure of cost-effectiveness of maintaining in-house services as opposed to contracting out some or all aspects of storage and distribution.

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[6] For example, the MSH *International Drug Price Indicator Guide*, published regularly, posts the tender results from reputable souces by product, and generates an average or median prices paid against which other programs can compare their own results. Available on-line at: http://www.msh.org/resources/publications/IDPIG_2004.html

♦ Shortage costs (e.g. value of emergency purchases) as a percentage of total costs, as a measure of the cost-effectiveness of procurement practices. High shortage costs relative to total costs should generate questions about why shortages occur (may be due to poor quantification, "mis-matched" budget cycles, excessive inventory loss due to expiry, theft or spoilage).

Armed with these various measures, the health system analyst is ready to characterize the effectiveness and efficiency of the pharmaceutical system and with an understanding of the functioning of the supply cycle, identify sources of those problems. Unfortunately, it may seem that such analyses cannot be performed properly because quality data is very difficult to come by, and in some cases it does not exist. When data is not available (non-existent or inaccessible) it may be possible to derive reasonable estimates by taking the time to become familiar with the cost structures in other agencies or organizations in the same or otherwise comparable context. With this information and a solid understanding of the particular socio-economic and political context, health planners can consider options for more realistic interventions.

IDENTIFYING OPPORTUNITIES AND CHALLENGES PRESENTED BY HEALTH SECTOR REFORM

The approach presented in this document begins with an understanding of the key functions of a pharmaceutical system and how to measure system performance. This provides the basis for the definition of performance problems and how they might be addressed through reform initiatives. Performance goals and targets, derived from the strategic prioritization of problems, ethical review, political and technical analyses, need to clearly defined and operationalized to be useful.

One of the challenges that planners and managers face is not to atomize the pharmaceutical system. Focusing on only one or two performance areas can blind one to the unintended impacts of initiatives in all components and levels of the system. While there are several opportunities for win-win situations, trade-offs are often required, especially when performance goals are not based solely on economic efficiencies. By the same token, although reform efforts that specifically target the pharmaceutical system share the same principals of the larger sector reform, analysts should be sensitive to the possibility of the existence of duplication of functions, unexpected gaps, and unnecessary costs (Romero, 2002).

This section discusses types of strategies for improving system performance. This section ends with a brief presentation of two country examples.

Instruments of reform applied to the pharmaceutical system

Four types of instruments or strategies through which reform initiatives aim to achieve their goals are described by Roberts et al (2004) and presented in Diagram 1. Specific to the reform of pharmaceutical systems, the instruments most commonly relevant to pharmaceutical system performance include:

Policy and legal framework: National medicine policies define the principles and values that guide the development of a pharmaceutical system such as the concepts of essential drugs, rational drug use, and equitable access. They should be consistent with or support the overall health policy. National medicines laws and regulations (such as national generics laws and registration) lay out the parameters for how specific functions and activities within the pharmaceutical system will be accomplished. This includes, for example, determination of what cadres of professionals and facilities are permitted to prescribe and dispense, what products will be permitted to circulate in the marketplace (public and private sectors), and how to import and export products. A common difficulty countries have in this regard is the lack of sufficient resources or political will to follow-through or enforcement.

Many initiatives may be seriously delayed or never implemented because they are not supported by or are contrary to a national policy or law. Existing laws that may need to be addressed are civil servant laws, importation and sales of pharmaceuticals, laws and regulations regarding qualifications of dispensers, and pricing procurement and policies. In some cases, the process for

introducing a new or change of a law is lengthy and initiatives risk proceeding before having the sanction of law, as is the case with the in Ecuador where several reform initiatives were implemented before a comprehensive supporting legal basis for them was adopted (Barillas, 2005b).

Financing mechanisms: Prior to reforms, most health systems in Latin America financed their pharmaceutical systems completely through the central MOH budget. Under reform initiatives that aim to expand access to previously unprotected populations these funds were clearly no longer sufficient, leaving two options that are not necessarily mutually exclusive: find new sources of revenue and improve the management (efficiency) with which existing funds are used. Reform initiatives have introduced alternative mechanisms that tend to shift some of the responsibility and burden and for financing closer to the facility and the user levels for cost recovery (revenue generating) purposes. Where financial responsibilities are decentralized or deconcentrated to lower levels, options include pooling resources for procurement (e.g., El Salvador). Cost recovery and cost sharing mechanisms that affect the patient include patient fees that cover medicines, pharmacy benefits programs, revolving funds. Unfortunately, many funds fail due to inadequate design or poorly implemented management controls (e.g., Peru). Pharmaceuticals may also be financed through donations in the form of capital or in-kind. For some countries, donated funds can account for as much as 40% of the budget for pharmaceuticals (e.g., Nicaragua). However, there are costs associated with receiving donations, and if donations are of products that are of poor quality or do not conform to the clinical needs of the population, they can cost more than they are worth.[7]

Organization of services: In order to meet the objectives of expanding access to quality care and to increase efficiencies, many health reforms in Latin America have considered options for privatizing or contracting for services. In those countries in which there is local capacity in the private sector and contract management capacity in the public sector, options could include contracting with the commercial sector for all or some of the key management functions. For example, systems may consider contracting with prime vendors or prime distributors for pharmaceutical procurement management, distribution (storage and transportation) management, and pharmaceutical utilization review. Other options include providing incentives for alternative sources of affordable essential medicines in regions neglected by the traditional commercial sector such as access to lower cost products (e.g., in Guatemala and Nicaragua).

Provider and consumer behavior: Behaviors that reforms aim to influence related to the use of pharmaceuticals, or, the demand side of the system, as much as the supply side related to the way resources are managed. The two key behaviors that are of particular relevance are prescribing and medication use. In general, there are three main types of interventions that aim to change behavior: managerial, educational and regulatory. Managerial interventions aimed providers are designed to guide diagnoses and prescribing and include tools such as standard treatment protocols, restricted formularies (such as essential medicines lists), audits and corresponding incentives. Managerial interventions to guide patients similarly include incentives for seeking generics instead of more expensive brand names. Educational interventions are based on the

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[7] A guideline document to help programs develop and enforce pharmaceutical donations has been developed by WHO may be found on http://www.who.int/medicines/library/par/who-edm-par-1999-4/who-edm-par-99-4.pdf.

assumption that when properly informed about appropriate behavior, people will change their behavior accordingly. Educational interventions include various types of continuing education programs for health care staff, informational brochures and pamphlets for both providers and patients. Regulatory interventions aim to coerce individuals to behave appropriately. Greater and more sustained changes are achieved when combinations of two or more types of interventions are used (Le Grand, et al., 1999; Radyowijati A and H Haak, 2003). Within the context of health sector reform in particular, opportunities for ensuring that providers and patients understand the need for rational pharmaceutical management (from selection through to use) are presented through the formation of multisectoral and local health councils and committees that include representatives from the community.

Country Examples

Guatemala – Improving efficiencies, affordability and geographic access through centralized tendering for prices by generic name, direct delivery and social pharmacies

In 1996, Guatemala initiated a rapid process of health sector reform that has had significant implications for the management of pharmaceuticals. Two main goals of the reform were to improve efficiencies of the Ministry of Public Health (MSPAS) and to address inequities in access to care, especially for the rural population. This followed the lead of the Peace Accords, which defined the social and economic priorities and values for the development of the country and based upon which the government adopted the strategy to "modernize."[8] Together, these two strategies gave impetus to the modification of the already existing open contract mechanism to allow for the procurement of generic medicines in the public sector. The procurement included terms for direct delivery to the local health authority (*Dirección de Area de Salud-DAS*). Extending coverage was to be achieved by contracting with NGOs working in rural areas and the Access to Medicines Program (see Diagram 4).

Health Sector Reform Strategies	Initiatives that Impact on Pharmaceutical System	Expected Impact	Evaluation Result
Deconcentration of administrative and financial functions to DAS	Procurement through Open Contract mechanism with direct delivery	Improved efficiencies through lower prices of medicines in public institutions and decreased distribution costs	✓ nearly 50% decrease in the prices of pharmaceuticals in the first tender and sustained; central store and transport eliminated
Health Services Modernization Program		Improved availability of medicines in public institutions	☒ No significant change
		Improved transparency in decentralized procurements that lead to increase efficiencies	✓ Multisectoral Commission responsible for ensuring transparency. No data on improved efficiencies
Program for Expansion of Services (SIAS) Contracting with NGO	Program to Improve Access to Medicines	Increased affordability of essential medicines in the private sector	✓ Average price of tracer items is 13 lower in social pharmacies compared to private pharmacies
		Improved geographic access to sources of quality products	✓ More than 300 social pharmacies established in rural areas

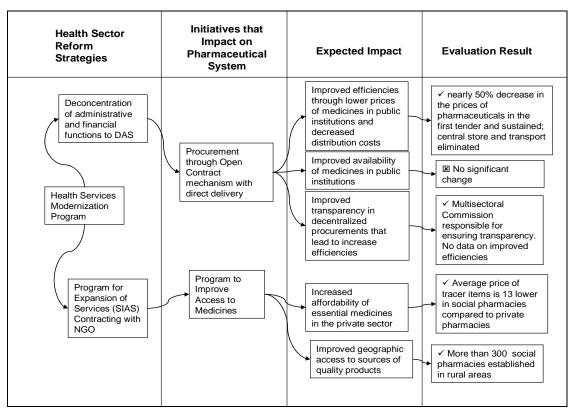Diagram 4. Reform Initiatives that aimed to impact on the pharmaceutical system in Guatemala. Adapted from Barillas (2005a).

Open Contract. The deconcentration of administrative and financial functions to the local health authority level (*Dirección de Area de Salud-DAS*), considered to be a stronger authority than the

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[8] This was a government-wide reform impacting all agencies, not just the MSPAS.

states, together with an increase in funds for the existing revolving drug fund for decentralized purchases, allowed for some critical improvements in payment lead times to suppliers. While suppliers could negotiate purchases directly with the DAS, the advantage to the DAS of economies of scale were lost. In order to regain it, the government modified the existing procurement mechanism known as the open contract (*contrato abierto*) to allow for the procurement of pharmaceuticals. Under this mechanism, tendering for prices by generic name is centralized (under the Ministry of Finance and Planning) based on combined quantities from the three main public institutions involved in procuring medicines. The winning suppliers contract with the government to sell the designated products, including delivery, for the adjudicated price, to the DAS.

The tender prices combined the price for the medicines and distribution to the DAS so it was not possible to compare the prices of medicines separately from the cost of distribution. However, the net gain to MSPAS from the first tender under the open contract mechanism over the previous completely decentralized approach is estimated to net approximately US$33 million.[9] This would not include the savings gained from the closing of the central medical store and elimination of MSPAS transportation services. It is not clear if there were cost implications to the DAS as a result of increased responsibilities, volume of inventory received, or new staff requirements.

The availability of essential medicines in the MSPAS health centers and posts did not improve significantly: from 60% in1992 to 68% 2002. The average length of time out of stock, however, decreased from 32% to 17%. It is not clear if the stock outs have been a result of poor inventory management or deficiencies on the part of suppliers.

Social pharmacies. In 1997 the MSPAS began contracting NGOs to provide basic health services in order to expand access of services, with the medicines supplied through the MSPAS and dispensed free of charge to patients. The NGOs were also permitted to establish not for profit pharmacies to sell essential medicines purchased from the NGOs, at open contract prices, known as social pharmacies (*venta social de medicamentos - VSM*). The VSMs located in the rural areas can add up to 35% to their purchase price for sale to the public while those located in the urban areas and add no more 33%.

Geographic access increased dramatically as the number of VSM grew from 50 at the outset of the program to 866 covering 35% of the population in 2004. Affordability was also addressed positively. In 1999, the prices of medicines in the private pharmacies were about 6 times greater than those sold in the VSM; in 2004 the difference doubled.

Challenges and opportunities: Among the greatest challenges to the implementation of the initiatives to improve the pharmaceutical system was the opposition expressed by some suppliers to the open contract. The open contract posed a threat to small scale vendors that depended on the particular relationships they had with their clients rather than having to compete on a tender. Their expressed concern was that the large suppliers with international connections would displace the smaller national firms, and thus would be contrary to the larger economic

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[9] These surplus funds were applied toward salary increases for MSPAS employees and contributed to the extension of coverage of basic services.

development goals of the country. In order to ensure that the suppliers concerns were heard and considered, they were invited to have representation on the Multisectoral Committee for Medicines that was responsible for ensuring that appropriate modifications were made.

Some providers also had expressed concerns about the possibility of opening the door to the procurement of poor quality generic medicines. In order to address this, the national quality control laboratory was moved, newly equipped, staff was retrained and new employees was hired.

A significant weakness in the system that also needed to be addressed was the capacity at the local level to properly estimate needs. The unreliability of the quantities was difficult for suppliers to cope with and generated distrust. It also affected payments. In response to this, MSPAS sought to hire a pharmacist for each DAS to develop procurement lists and quantities. Now, when shortages occur they are said to be more likely due to failures on the part of suppliers not being able to keep up with demand.

Ecuador – Centralized procurement with local purchases, price controls, cost recovery and protection for special groups, legal framework

Health sector reform in Ecuador may be characterized as a series frustrated efforts, driven largely by forces outside the health sector itself and directed to the broader social and political reform movement. Most initiatives that relate in any way to the pharmaceutical system were not directed specifically to it. The initiatives that potentially could impact on the performance of the pharmaceutical system are presented in Diagram 5, although some have been implemented too soon to evaluate.

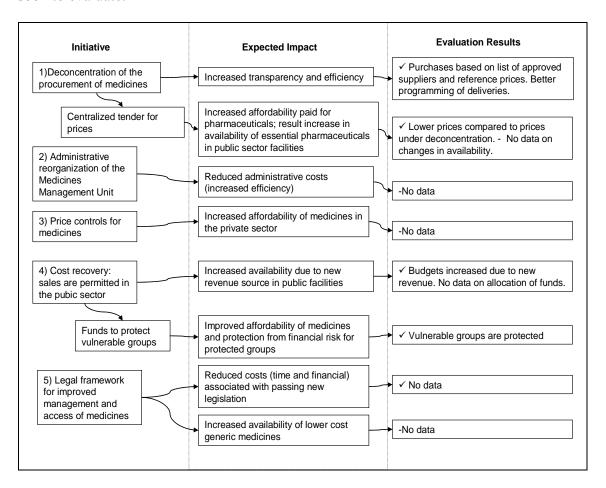| Initiative	Expected Impact	Evaluation Results
1) Deconcentration of the procurement of medicines	Increased transparency and efficiency	✓ Purchases based on list of approved suppliers and reference prices. Better programming of deliveries.
Centralized tender for prices	Increased affordability paid for pharmaceuticals; result increase in availability of essential pharmaceuticals in public sector facilities	✓ Lower prices compared to prices under deconcentration. - No data on changes in availability.
2) Administrative reorganization of the Medicines Management Unit	Reduced administrative costs (increased efficiency)	-No data
3) Price controls for medicines	Increased affordability of medicines in the private sector	-No data
4) Cost recovery: sales are permitted in the pubic sector	Increased availability due to new revenue source in public facilities	✓ Budgets increased due to new revenue. No data on allocation of funds.
Funds to protect vulnerable groups	Improved affordability of medicines and protection from financial risk for protected groups	✓ Vulnerable groups are protected
5) Legal framework for improved management and access of medicines	Reduced costs (time and financial) associated with passing new legislation	✓ No data
	Increased availability of lower cost generic medicines	-No data

Diagram 5: Adapted from Barillas (2005b).

The two central themes for reform in Ecuador, as with most other countries in the region, are modernization and decentralization, with the aim to improve efficiencies and to address social inequities. Since the beginning of the 1990's, initiatives started to be implemented to achieve these goals. It was not until 1998 however, that the National Health Policy was published, allowing for a clear statement of health priorities and strategies to address them.

Since the early 1990's, administrative financial responsibilities were increasingly deconcentrated to the hospitals and to provincial health areas, collectively known as operative units (*unidades operativas* – UO), including for cost recovery for medicines, which remained a key strategy.

Other sources of funds for UO included an annual budget from the MOH, special funds received through a program specifically for maternal and child health. Social participation in health services management decision making was to occur through provincial and canton level health councils and the committees for social participation, sanctioned in 1999.

Desconcentration with centralized procurement: As is often the case, the deconcentration of functions yielded some benefits although, at considerable cost. Although not well documented, it is likely that local procurement resulted in an increased level of effort for staff and a loss of economies of scale. As a corrective measure, the MOH decided to implement centralized procurement for prices to be realized through local purchase. As per the Generics Law, passed in 2000, the products to be procured had to be generics. The first tender for prices took place in 2004.

According to Barillas (2005b) there is evidence to suggest that availability improved at least in part due to the introduction of decentralized procurement: in 2004 the average availability of a set of tracer items had increased 37%, up from 46% in 1993. The average time out of stock over a period of 12 months decreased to 8%, from12% in 1993. However, Barillas also notes that the more remote areas still ran greater risk of more and longer stockouts.

Price controls: The system for price controls aimed to set ceilings for prices for medicines sold to the public in private pharmacies. The ceilings were supposed to be calculated on the basis of the costs of production. In principle, price controls World aim to ensure against price gauging. Unfortunately there is insufficient data, and some question the validity of existing data, to determine if the prices to the public were controlled or reduced in any way because of this intervention.

Cost-recovery and funds to protect vulnerable groups. The receipts from the sale of medicines to patients contribute to the overall budget of the OU. However, the expenditures on medicines have grown exponentially compared to receipts, indicating that other funds (from the MOH and/or the maternal and child health program) have become more important, and therefore that vulnerable groups are being protected. Anecdotal evidence suggests that the number of patients exempted from payment has been increasing.

Challenges and opportunities: Ecuador has only recently implemented some initiatives that potentially could impact significantly the availability of quality, low cost medicines. It is not clear if information systems are in place to monitor and evaluate changes over time on key performance indicators. The high level of political instability in the country has proved to be a significant challenge to the reform efforts. One can only hope that armed with good evidence of the performance of the pharmaceutical system, management decisions can supersede politics.

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